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Request for grant of a patent

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The Patent Office
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1. Your reference — P31110-/CPA/RTH/RMC

2. Patent application number *(The Patent Office will fill in this part)* — 0208359.0

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Gyne Ideas Limited
1 Bell Leys
Wingrave
Buckinghamshire HP22 4QD
United Kingdom

Patents ADP number *(if you know it)* 8244642001

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — "Apparatus and Method for Treating Female Urinary Incontinence"

5. Name of your agent *(if you have one)*

Murgitroyd & Company

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Scotland House
165-169 Scotland Street
Glasgow
G5 8PL

Patents ADP number *(if you know it)* 1198013

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Yes

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Continuation sheets of this form	
Description	30
Claim(s)	-
Abstract	-
Drawing(s)	8

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Priority documents	
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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Murgitroyd & Company Date 11 April 2002

Murgitroyd & Company

12. Name and daytime telephone number of person to contact in the United Kingdom — Roisin McNally — 0141 307 8400

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"Apparatus and Method for Treating Female Urinary Incontinence"

The present invention relates to an apparatus and method for treating female urinary incontinence. In particular, a surgical implant that passes under the urethra in use and supports the urethra, the implant being anchored in the retropubic space is provided.

Urinary incontinence affects a large number of women and, consequently, various approaches have been developed to treat female urinary incontinence. Those skilled in the art will be familiar with approaches ranging from pelvic floor exercises to surgical techniques such as Burch colposuspension and Stamey-type endoscopic procedures in which sutures are placed so as to elevate the bladder neck.

This invention is particularly directed to improvement of a known procedure in which a sling is positioned loosely under the urethra, commonly known

as TVT (tension free vaginal tape) and described, for example, in International Patent Applications No. WO97/13465 and WO97/06567. It is generally understood that this treatment alleviates urinary incontinence by occluding the mid-urethra (for example at a time of raised abdominal pressure by coughing or the like).

In order to provide a sling loosely under the urethra using the apparatus and method of the prior art an incision is made in the anterior vaginal wall and a first needle is passed through the incision, past one side of the urethra, behind the pubic bone, through the rectus sheath and out through the lower anterior abdominal wall. Likewise, a second needle is passed through the incision, past the other side of the urethra, behind the pubic bone, through the rectus sheath and out through the lower abdominal wall. The needles are separated from their respective insertion tools and also from the mesh or tape such that only the tape and its plastics sleeve are left in the body, passing from a first exit point in the lower abdominal wall, through the rectus sheath, behind the pubic bone, under the urethra, back behind the pubic bone, back through the rectus sheath and out through a second exit point in the lower abdominal wall.

The plastics sleeve is then removed from the tape and the tape adjusted to a suitable tension (such that the tape provides a sling that passes loosely under the urethra, as described above) by

manoeuvring the free ends of the tape outside the exit points in the lower abdominal wall whilst the urethra is held using a rigid catheter inserted therein. The tape is then cut such that it just falls short of protruding from the exit points in the lower abdominal wall. The exit points and the incision in the upper vaginal wall are then closed by sutures.

Whilst highly effective in treating urinary incontinence, this procedure has a number of problems. One such problem is that the needles used for inserting the tape are comparatively large, with the needles having, for example, a diameter of around 5-6 mm and a length of around 200 mm. As well as causing concern for patients viewing such needles before or in some cases during the procedure, the size of the needles can also lead to a high vascular injury rate.

Similarly, the requirement that the needles exit the lower abdominal wall is disadvantageous due to the trauma to the patient in this area and the pain of such abdominal wounds. A further disadvantage is that, as the tape is required to extend from the lower abdomen wall under the urethra and back through the lower abdomen wall, the tape must comprise a relatively large foreign body mass (typically around 25 to 28 cm) to be retained within the patient. This can lead to related inflammation, infection translocation, erosion, fistula and such like.

Similarly, the nature of the large needles and tape, along with the tools required to insert these in the body, lead to the procedure having a relatively high cost.

Further details of the apparatus and methods of the prior art are provided in the co-pending International Patent Application No PCT/GB01/04554.

It would be advantageous if a surgical implant such as a sling could be inserted into the body such that it is positioned loosely under the urethra without requiring penetration of the abdominal wall or rectus sheath. Most of the pain associated with previous procedures to introduce a surgical implant as described above is due to the force required to penetrate the tough structures of the abdominal wall or rectus sheath, both of which are highly innervated. The suitable location of a surgical implant such that it hangs loosely under the urethra without requiring penetration of the lower abdomen or rectus sheath would reduce the trauma experienced by the patient. Further, a greater number of major blood vessels are located in the retropubic space towards the rectus sheath that toward the endopelvic fascia and thus by suitably locating the implant, without piercing the rectus sheath, damage to these blood vessels would be minimised. This would reduce the amount of bleeding experienced by the patient.

In addition, such location of a surgical implant with a reduced level of trauma may allow the

procedure to be performed under local anaesthetic in an out patient or office setting.

Ideally a surgical implant such as a sling used to treat female urinary incontinence includes means to adjust the position of the suburethral portion of the sling such that this portion passes under the urethra and is able to occlude the mid urethra at times of raised abdominal pressure. In addition, the surgical implant should have minimal mass, when implanted in the body, to reduce the likelihood of inflammation and the like as discussed above.

According to the present invention there is provided a surgical implant for supporting the urethra, the implant comprising a flat tape including two fixing zones and a supporting zone, the supporting zone being interposed between the fixing zones and the fixing zones each having at least one retaining means for anchoring the fixing zones in the tissues of the retropubic space, without penetrating the rectus sheath such that in use the supporting zone passes under the urethra.

The fixing zone of the surgical implant must be anchored in the tissues of the retropubic space with adequate tensile strength to counter dislodging by coughing until suitable integration of tissue occurs.

Preferably each fixing zone comprises a plurality of retaining means.

Preferably the fixing zones are tapered

Preferably the retaining means comprise a plurality of projections extending laterally from the longitudinal axis of the implant.

More preferably the projections extend from the longitudinal axis of the implant such that they point away from the bladder when the surgical implant is positioned such that the supporting zone passes under the urethra.

Preferably the projections are curved such that they point away from bladder when the surgical implant is positioned such that the supporting zone passes under the urethra.

Preferably the surgical implant is curved such that the longitudinal edges of the fixing zone of the implant and thus the projections of the retaining means in use are directed away from the bladder.

Curvature of the longitudinal edges of the fixing zone such that they are directed away from the bladder minimises medial presentation of the retaining means such as projections to the bladder minimising erosion of the bladder.

Preferably the fixing zone comprises the shape of a serrated arrowhead the base portion of the arrowhead conjoined to the supporting zone.

Alternatively the retaining means is glue.

Preferably the glue is cyanoacrylate glue.

Preferably the surgical implant is comprised of resilient material such that if the surgical implant is not restrained it adopts the original shape defined during production of the surgical implant.

Preferably the surgical implant is comprised of plastics material.

More preferably the surgical implant is comprised of polypropylene.

Alternatively the surgical implant is comprised of absorbable material.

Preferably the surgical implant is of length 6 to 22 cm.

More preferably the surgical implant is of length 8 to 20 cm.

Most preferably the surgical implant is of length 10 to 15 cm.

Preferably each fixing zone is of at least 1 cm in length and not greater than 8 cm in length.

More preferably each fixing zone is 5 cm in length.

Preferably the supporting zone is of at least 2 cm in length.

Preferably the surgical implant is of width 0.5 cm to 1.5 cm.

More preferably the surgical implant is of width 0.5 cm to 1cm.

Most preferably the surgical implant is of width 0.8 cm.

The surgical implant is of suitable length such that a first fixing zone can be secured in the tissues of the retropubic space and the implant can extend from the tissues of the retropubic space, pass on one side of the urethra such that the supporting zone of the implant passes under the urethra and a second fixing zone passes on the other side of the urethra and into the tissues of the retropubic space, such that the second fixing zone can be secured in the tissues of the retropubic space. Preferably the fixing zones are positioned only as far into the tissues of the retropubic space as required such that pressure transmission occurs and the mid-urethra is occluded at periods of raised abdominal pressure such as coughing.

It is preferable that tissue growth around and through the surgical implant occurs to integrate the surgical implant into the body.

Fibroblastic through growth around the implant secures the implant in the body increasing the support provided by the surgical implant.

Preferably at least one of the fixing zones of the surgical implant is provided with means to improve fibroblastic through growth into the surgical implant.

Preferably the means to improve fibroblastic through growth comprises pores which extend through the fixing zone material said pores ranging in width across the surface of the fixing zone from 50μm to 200μm.

More preferably the pores are a width of 100 μm.

Alternatively the means to improve fibroblastic through growth comprises pits, that indent at least one surface of the fixing zone, but do not extend through the fixing zone, the pits ranging from 50 to 200 μm in width.

More preferably the pits are 100 μm in width.

Preferably the pits or pores are distributed across the complete surface of at least one of the fixing zones.

Alternatively the pits or pores are distributed only in a particular portion of the surface of at least one of the fixing zones.

Preferably the pits or pores are created by post synthesis treatment of at least one of the fixing zones by a laser.

Alternatively the pits or pores are created during synthesis of at least one of the fixing zones.

Where the fixing zone is comprised of plastics material the pits or pores may be formed by the spaces of mono-filament between the waft and weave of mono-filament or multi-filament yarns when the filaments are woven to form a mesh.

Alternatively pits or pores formed during the synthesis of plastics material are formed by the inter-filament spaces created when mono-filaments are twisted to create multi-filaments, the multi-filaments then being woven to form a mesh.

Preferably integration of the surgical implant into the body via fibrous tissue through-growth begins to occur within one month of insertion of the surgical implant in the body.

More preferably integration of the surgical implant into the body via fibrous tissue through-growth begins to occur within two weeks of insertion of the surgical implant in the body.

It is also advantageous that lay down of collagen fibres occurs in an ordered direction to promote the formation of at least one strong ordered neoligament. The formation of at least one ordered neoligament aids the support of the urethra provided by the implant by adding mechanical strength to tissue which forms around the surgical implant.

Preferably at least one of the fixing zones is provided with a plurality of microgrooves of width between 0.5-7 μm and of depth 0.25-7 μm on at least one surface of the fixing zone.

More preferably the microgrooves are 5 μm in width and 5 μm in depth.

Preferably the plurality of microgrooves are aligned such that they are substantially parallel with each other.

Preferably the plurality of microgrooves are aligned such that they are separated by ridges which range in size between 1-5 μm in width.

More preferably the microgrooves are separated by ridges of 5 μm in width.

Preferably the ridges are formed by square pillars and the base of the microgroove is substantially perpendicular to the square pillars.

Alternatively the ridges are formed by square pillars and the base of the microgroove is bevelled in relation to the pillars.

Preferably the microgrooves are present on at least one surface of the fixing zone.

More preferably the microgrooves are present on a plurality of surfaces of the fixing zone.

Preferably the supporting zone of the surgical implant does not comprise pores or pits.

Preferably only the surfaces of the supporting zone not brought into contact with the urethra comprise microgrooves.

The supporting zone is not provided with pores or pits to discourage the formation of peri-urethral adhesions.

Preferably at least one fixing zone is capable of being moved in and out of the tissues of the retropubic space by a surgeon.

Preferably movement of the fixing zone into and out of the tissues of the retropubic space allows adjustment of the location of the supporting zone such that it passes under the urethra.

Preferably each fixing zone comprises at least one aperture adapted to receive and co-operate with a tool for insertion of the implant into the body.

The invention also provides a tool for inserting the implant into the body the tool comprising an elongate shaft including a semi-blunt point at a first end and a handle at a second end and holding means to releasably attach the shaft to the surgical implant.

Preferably the elongate shaft is curved or bent, through an angle of approximately 30°.

Preferably the elongate shaft of the tool is of length 6 to 15 cm.

More preferably the elongate shaft of the tool is 8 cm in length.

Preferably the elongate shaft of the tool is between 2-3 mm in diameter.

Preferably the holding means comprises a recess extending from the semi-blunt point of the elongate shaft the recess capable of receiving a portion of the surgical implant.

Preferably the recess is angled to twist a surgical implant received by the recess along its longitudinal length such that the longitudinal edges

of the fixing zone of the surgical implant are directed away from the bladder.

Twisting of the surgical implant such that the edges of the fixing zone are directed away from the bladder minimises medial presentation of the retaining means to the bladder.

Alternatively the holding means comprises an abutment located toward the first end of the elongate shaft wherein the semi-blunt point of the elongate shaft is capable of being passed through the surgical implant and the abutment is capable of hindering movement of the surgical implant down the length of the shaft toward the second end of the elongate shaft.

Preferably the tool is comprised of plastics material.

Alternatively the tool is comprised of surgical steel.

Preferably the handle is circular in shape and is mounted perpendicular to the curvature at the second end of the elongate shaft.

According to a second aspect of the present invention there is provided a method of supporting the urethra comprising the steps of;

introducing a surgical implant of any of the preceding claims into an incision made on the upper wall of the vagina,

inserting a first end of the surgical implant behind the first side of the urethra,

locating a first fixing zone into the tissues of the retropubic space without penetrating the rectus sheath,

inserting a second end of the surgical implant behind a second side of the urethra, and

locating a second fixing zone into the tissues of the retropubic space without penetrating the rectus sheath, such that the supporting zone passes under the urethra.

Embodiments of the present invention will now be described by way of example only, with reference to the accompanying drawings in which;

Figure 1 shows a diagrammatic view of the surgical implant,

Figure 2 shows a diagrammatic side view of the surgical implant,

Figure 3 shows retaining means which may be present at the fixing zone,

Figure 3b shows an illustration of the tape in cross section,

Figure 4 shows a diagrammatic view of the retropubic space, related to needle passage for any pubo-vaginal sling,

Figure 5 shows an illustration of an introducing tool,

Figure 6 shows an illustration of a further embodiment of an introducing tool, and

Figure 7 shows an illustration of the position of the tape in relation to the bladder taken from a superior view.

Referring to figure 1 the surgical implant is a flat tape 2 which has a supporting zone 4 interposed between two fixing zones 6 the fixing zones being discrete zones of fixation extending from the supporting zone 4 to the first 8 and second 10 ends of the tape 2 respectively. Apertures 11 extend through the tape 2 at the first and second ends of the tape 2. These apertures 11 are of suitable size to allow a portion of an introducing tool to be passed through the apertures 11.

The surgical implant may be 14 cm in length and 1 cm in width, the supporting zone being around 4 cm in length such that it is able to pass under the urethra.

In this example, the surgical implant is made from flat polymer tape. The tape may be comprised of polypropylene.

As shown in figure 3 the longitudinal edges 30,32 of the fixing zone 6 may be tapered such that the width of the fixing zones increases from the first and second ends 8,10 of the fixing zones to the supporting zone. The tapered nature of the fixing zones 6 minimises disruption of the tissue of the retropubic space during placement of the tape 2 by the surgeon.

The projections of the retaining means in the embodiment shown in figure 3 are curved such that they extend from the longitudinal axis such that in use the projections are not medially presented to the bladder which lies anterio-medially in respect to the passage of tape 2 in the body.

Further as shown in figure 3b the tape 2 may be of curved or of convex construction such that retaining means such as the projections shown face in a direction opposite or away from the bladder in use. The curvature of the tape therefore ensures that the projections lie postero-laterally of the anterio-medial bladder position. This positioning minimises the possibility of bladder erosion by the tape following placement.

The tape of the supporting zone has smooth edges to avoid adhesion of the supporting zone of the tape to the urethra.

The polypropylene tape 2 of the fixing zone 6 comprises pores 12, ranging in width from 50μm to 200μm, that extend through a first surface 14 to a second opposite surface 16 of the tape 2. The pores 12 may be formed by post synthesis treatment of the fixing zones of the tape 2 with a laser.

The pores 12 promote fibroblastic through-growth and lay down of tissue around and through the tape 2. This aids integration of the fixing zone of the tape 2 to the tissue of the retropubic space.

The pores 12 may be created by post synthesis treatment of the fixing zones 6 of the tape 2 by a laser.

In addition to the pores 12, in the embodiment shown the fixing zone also comprises microgrooves 18 of width 5μm and of depth 5μm. These microgrooves 18 are shown present on one surface 14 of the fixing zone of the tape 2, but may also be present on the opposite surface. The microgrooves 18 are aligned such that they are substantially parallel with each other and separated by ridges 24 of around 5μm in width.

The ridges 24 are formed by square pillars the base 26 of the microgroove 18 being substantially perpendicular to the square pillars.

The microgrooving promotes orientation and alignment of proliferating fibroblasts on the surface 14 of the tape 2 of the fixing zone 6 and promotes axial alignment of collagen fibres and formation of at least one strong ordered neoligament. The orientation and alignment of the proliferating cells adds mechanical strength to the tissue which form around the tape such that these tissues support the urethra.

The supporting zone 4 of the tape 2 is not provided with pores or pits to discourage the formation of peri-urethral adhesions. Micro-grooving is provided only on the surfaces of the supporting zone not brought into contact with the urethra in use.

As discussed urinary incontinence may be caused if the pelvic floor muscles and connective tissue cannot support the bladder neck and mid-urethra, when pressure on the bladder is exerted from the diaphragm. Increased intra-abdominal pressure may occur at times such as coughing. The increased abdominal pressure results in the urethra descending from its normal position and failing to retain its seal, permitting urine to escape.

Previous apparatus and methods used for locating a surgical implant such that the implant hangs loosely

under the urethra have generally required that the implant be suspended from either the lower abdominal wall, the rectus sheath or other defined anatomical support structures as the tissues of the retropubic space and endopelvic fascia were not deemed to provide enough resistance to allow appropriate location of a surgical implant such that suitable support would be provided to occlude the mid-urethra at periods of raised abdominal pressure, by coughing or the like.

Suitable support can however be provided by the tissues of the retropubic space if fixation of the surgical implant is achieved in the tissues of the retropubic space.

As shown in figure 6 the retropubic space is an extraperitoneal tissue space lying behind the pubic bone. The retropubic space is defined by an anterio -superior boundary which is the peritoneum and rectus sheath and an interior boundary of endopelvic fascia. The space defined by these boundaries is medially filled by the bladder, the urethra, fibro-fatty tissue and blood vessels. The blood vessels of the retropubic space generally become larger both in a superior and lateral direction within the retropubic space. The retropubic space approximately extends 8 cm from the endopelvic fascia to the rectus sheath, this distance varying by around 2 cm depending on the individual. The retropubic space comprises the same pressure compartment as the abdomen.

To locate the supporting zone 4 such that it passes loosely under the urethra it is required that the fixing zones 6 are fixed in the tissues of the retropubic space with as little tissue invasion as possible, but such that pressure transmission to the tape is maintained. A number of different retaining means can be envisaged including a christmas tree design (a), a brush (b), a fish hook (c), a triple hook (d), an umbrella (e), one or more rods with memory (f), a corkscrew (g), an inflatable balloon (h), an inflatable flat star (i), a bear trap (j), a bulldog clip (k), a mesh cylinder (l), a buckie ball (m), a staple (n), a barbed portion of tape (o), a sponge (p) or fibre entanglement method (q) to secure the fixing zones of the surgical implant into the tissues of the retropubic space. It should also be noted that a plurality of retaining means may be located alone or in combination along a substantial part of the fixing zone.

In a first embodiment, retaining means 20 are a plurality of projections 22 extending laterally from the longitudinal axis of the implant. These projections 22 are arranged along a substantial portion of the length of the fixing zone 6 such that when located in the tissues of the retropubic space they provide resistance at multiple levels within the fibro-fatty soft tissue and blood tissues of the para-urethral tunnel in a direction opposite to that in which the fixing zone 6 of the tape 2 is introduced into the tissues.

Due to the multiple layers of fixation that can be achieved using the plurality of retaining means 22 along a substantial length of the fixing zone 6 it is not necessary to insert the fixing zone through the rectus sheath. The fixing zone 6 is movable within the tissues of the retropubic space by the surgeon during placement of the tape 2 to allow suitable positioning of the supporting zone 4 under the urethra. The retropubic space typically ranges between 8 cm ± 2 cm defined by the boundaries discussed thus the fixing zone 6 may be inserted at various positions within the fibro-fatty tissue of the retropubic space. This provides a means of adjustment of the position of the supporting zone 4 in relation to the urethra. The tape 2 may be moved by a surgeon during placement of the tape in the body into and out of the tissues of the retropubic space to suitably locate the supporting zone in relation to the urethra.

As shown in figure 3 the projections 22 which form the retaining means 20 are curved such that the points 24 of the projections 22 are directed away from the supporting zone and the bladder.

The embodiment of the surgical implant described herein may be suitably located in the tissues of the retropubic space using an introducing tool.

As shown in figure 6 one embodiment of the introducing tool 50 comprises a handle 52 an elongate shaft 54 and a semi-blunt point 56, the

handle 52 being located at a first end 58 of the elongate shaft 54 and the semi-blunt point 56 being located at a second end 60 of the elongate shaft 54. The elongate shaft 54 is curved through an angle of approximately 30° to facilitate positioning of the fixing zone 6 of the surgical implant in the tissues of the retropubic space of the human body from an incision in the upper wall of the vagina. A narrowed portion 62 of the elongate shaft 54 extends from the semi-blunt point 56 toward the handle 52. An abutment 64 is formed where the shaft widens from the narrowed portion. The narrowed portion of the tool is able to be passed through the aperture 11 present in the fixing zones 6 of the tape 2. The abutment 64 prevents the movement of the tape 2 down the full length of the elongate shaft 54 such that the tape 2 is retained on the narrowed portion 62 of the elongate shaft 54, the semi-blunt point 56 extending through the aperture 11 in the tape 2.

An alternative embodiment of the tool, shown in figure 7 comprises a recess 70 which extends from the semi-blunt point 56, the recess being adapted to receive a fixing zone 6 of the surgical implant. The recess may be angled or offset such that when the fixing zone of the tape is positioned in the recess 70 of the tool the tape is twisted along its longitudinal length such that on placement of the tape within the tissues of the retropubic space the projections of the fixing zone face postereo-laterally of the anterio-medial bladder position.

Figure 8 shows an illustration of the direction of the retaining means in relation to the bladder.

The introducing tool 50 may be comprised of any suitable material. In the embodiments shown the tool 50 is 8 cm in length and 2-3 mm in diameter and is comprised of hard plastic. The tool may be disposable or capable of being sterilised.

With regard to the first embodiment of the tool. In use the semi-blunt point 56 is passed through the aperture 11 in the tape 2 such that the tape 2 rests on the abutment 64 preventing the tape 2 from moving further down the elongate shaft 54 of the tool 50. The tape 2 is rolled about its longitudinal axis such that the edges 30,32 are brought toward each other. The tape 2 is restrained in this rolled position. The tape 2 may be restrained by the surgeon or by an envelope placed over the rolled tape. An envelope placed over the rolled tape may comprise a medial defect, which allows removal of the envelope when the tape is suitably positioned, by pulling the tape through the defect in the envelope.

The rolled fixing zone 6 of the tape 2 is inserted via an incision in the anterior vaginal wall, past one side of the urethra and into the retropubic space. Ideally insertion of the fixing zone 6 into the tissues of the retropubic space should be as limited as possible, but sufficient to allow suitable location of the fixing zone 6 and adequate

pressure transmission to allow occlusion of the urethra. Following insertion of the first end of the tape 2 the fixing zone 6 may be moved within the tissues of the retropubic space by the surgeon such that the fixing zone 6 is suitably located in the fibro-fatty soft tissue. Withdrawal of the introducing tool 50 described above causes the narrowed portion 62 of the tool 50 to be retracted from the aperture 11 of the tape 2. This causes release of the tape 2 from the tool. The tape may also be released from its restrained position by the surgeon. As the implant is formed from resilient material, which has memory, release of the implant from its restrained rolled position causes the longitudinal edges 30,32 to expand outwards, away from each other, from the rolled position such that the retaining means, the plurality of projections 22 at multiple layers, are pushed into the surrounding tissues of the retropubic space.

With regard to the second embodiment of the introducing tool discussed, in use, an aperture 11 in the tape 2 is passed over the semi-blunt point 56 such that a portion of fixing zone 6 of the tape 2 is retained in the recess 70, while the rest of the tape 2 comprising the supporting zone and a second fixing zone lies along the longitudinal length of the tool. As discussed the recess 70 of the introducing tool may be angled such that the fixing zone 6 retained within the recess 70 is orientated such that on placement of the fixing zone 6 in the tissues of the retropubic space the retaining means

20 of the fixing zone 6 face away from the bladder to minimise the risk of erosion of the bladder by the retaining means.

Introduction of the implant into the body using the second embodiment of the tool described is similar to that previously described. Release of the fixing zone 6 of the tape 2 from the recess 70 is performed by withdrawal of the tool.

The serrated arrowhead shape of the fixing zone of the embodiment described, means that as the fixing zone is pushed into a suitable location by the surgeon using the introducing tool, the distortion of the tissue in which the fixing zone is to be placed is minimised. This ensures that the retaining means of the fixing zone is provided with suitable tissue in which to obtain multi-level fixation. The fixation being of adequate tensile strength against cough until fixation of the implant by tissue through-growth occurs.

Following insertion and suitable placement of the fixing zone 6 of the tape 2, penetration of the fibro-fatty tissue by the multiple projections 22 occurs at multiple levels in the tissue and increases the grip of the retaining means 20 on the fibro-fatty soft tissue of the retropubic space. As the entry of the retaining means 20 is active and not passive, actively inserting the retaining means 20 into the tissue, the gripping effect of the plurality of the projections 22 is increased.

A second fixing zone comprising retaining means 20 as described for the first fixing zone is rolled such that the longitudinal edges 30,32 are brought toward each other. The surgical implant is restrained in this rolled position and inserted through the same incision in the vaginal wall as the first fixing zone, past the other side of the urethra and the rolled second fixing zone 6 released to allow the retaining means to grip the tissues of the retropubic space. The supporting zone 4 of the tape 2 being suitably located and held in position by the fixing zones 6 to provide support to the urethra.

In a second embodiment of the present invention retaining means are provided by glue.

Suitable glue such as cyanoacrylate glue or butyl acrylate glue may be applied to the fixing zone 6 of the tape 2. The glue is not applied to the supporting zone 4 of the tape 2, to ensure that the supporting zone 4 does not bind to the urethra.

In use cyanoacrylate glue is applied along a substantial length of a first fixing zone 6 of the tape 2 and this first fixing zone 6 is inserted through an incision in the anterior vaginal wall, past one side of the urethra into the retropubic space. Following insertion of the first end 8 of the surgical implant such that the fixing zone 6 is suitably located in the fibro-fatty soft tissue of the retropubic space, the tape 2 is held to enable

an adhesive bond to form between the fixing zone 6 of the tape 2 and the tissues of the retropubic space. As the glue is applied along a substantial length of the first fixing zone 6 the first fixing zone 6 adheres to the fibro-fatty soft tissue of the retropubic space at multiple layers providing suitable resistance.

Cyanoacrylate glue can then be applied along a substantial portion of a second fixing zone 6. The second fixing zone 6 can then be inserted through the same incision in the vaginal wall and past the other side of the urethra such that the supporting zone 4 is located to provide support to the urethra.

Further embodiments of retaining means can be envisaged such as swelling hydrogels such as gelatin, polysaccharides or Hyaluronic acid. These may be applied to the fixing zone 6 of the surgical implant, such that following introduction of the fixing zone 6 of the implant into the body the hydrogel expands, providing resistance in a direction opposite to that in which the fixing zone 6 of the surgical implant is introduced into the tissues, suitably locating the supporting zone 4 to support the urethra.

In addition retaining means may be substances which have properties changed by heat, cold or light that may be applied to the fixing zone 6 of the surgical implant such that on suitable treatment of the surgical implant, the fixing zone 6 of the implant

becomes suitably fixed in tissues of the retropubic space.

The length of the implant of the present invention is considerably less than that described in the prior art, which is typically 25 to 28 cm in length. This is of considerable advantage as the amount of foreign material placed in the body is reduced, decreasing the risk of inflammation and other problems associated with leaving foreign material in the human body for periods of time.

In addition as the present invention does not require the highly innervated and tough structures of the lower abdomen wall or rectus sheath to be punctured, which require considerable force to be applied by the surgeon, to enable location and fixing of the implant the trauma suffered by the patient is considerably reduced. Due to the decreased trauma suffered by the patient the above procedure may be carried out under local anaesthetic in an outpatient or office setting.

As a greater number of major blood vessels are found located in the retropubic space toward the rectus sheath, suitable placement of the anchor lower in the retropubic space minimises damage to blood vessels, reducing the amount of blood which might be lost by the patient.

Further, as there is not a requirement to anchor the fixing zone of the tape toward the rectus sheath,

the tape can be placed lower and more laterally in the retropubic space toward the endopelvic fascia this reduces the chance of damage to anatomical structures such as the bladder. In view of the decreased risk of damaging the bladder the described procedure may be performed without the need for per operative cystoscopy. This reduces the overall time taken to perform the procedure, further reduces the pain and trauma suffered by the patient and reduces the expense of the procedure.

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Figure 1

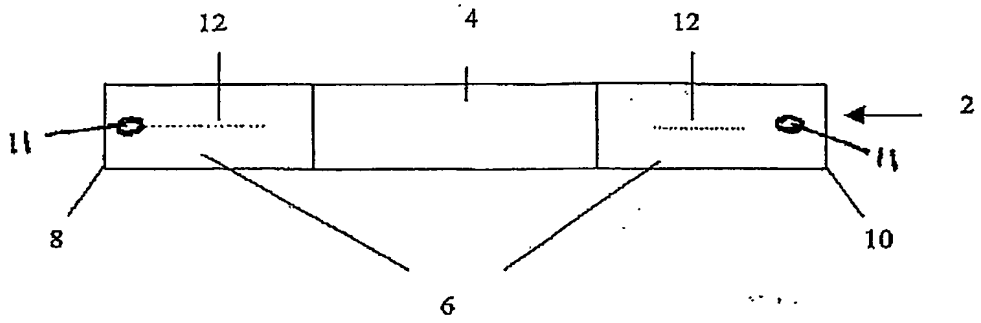

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Figure 2

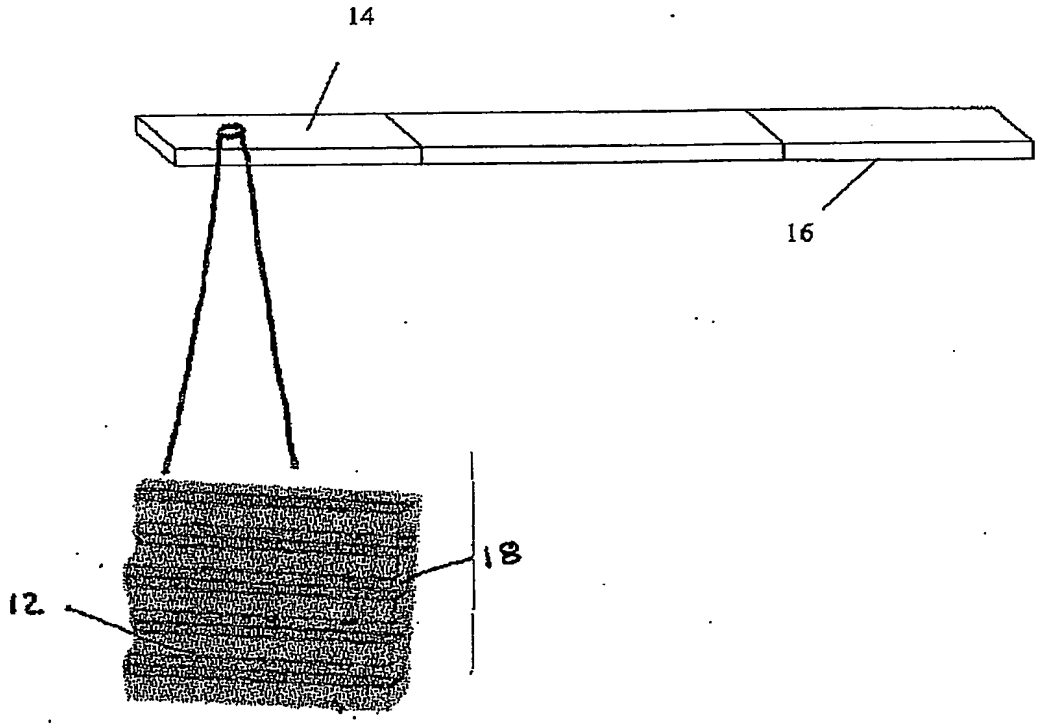

Figure 3

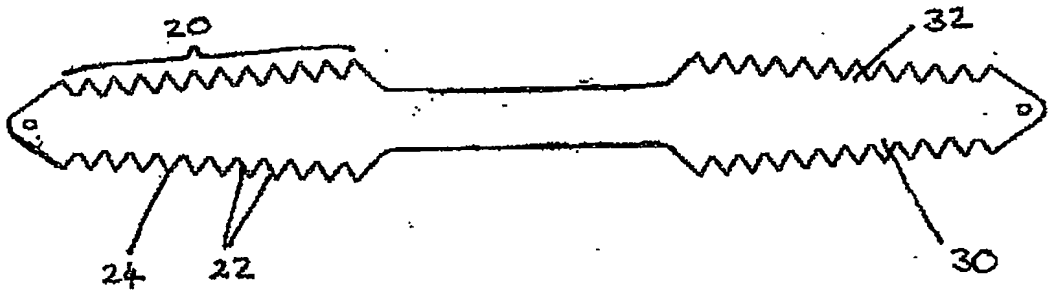

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Figure 3b:

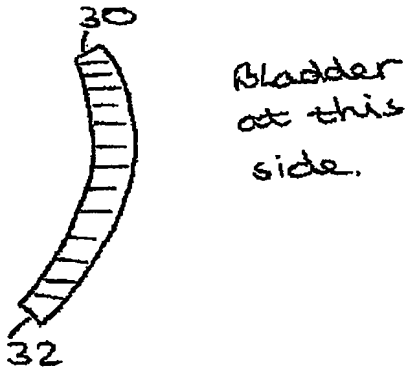

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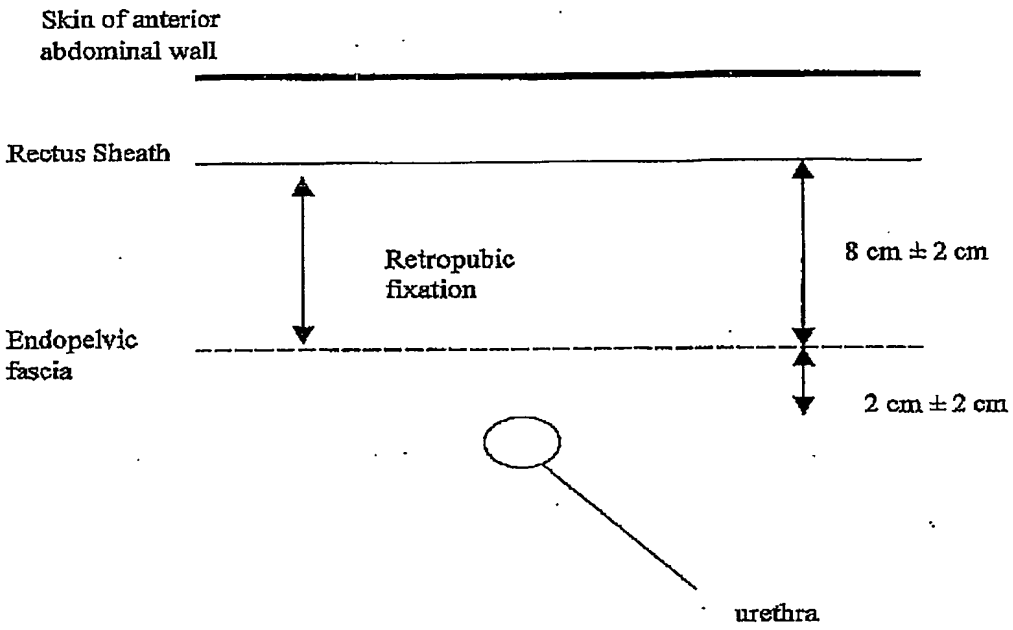
Figure 4 – Diagrammatic representation of Retropubic space



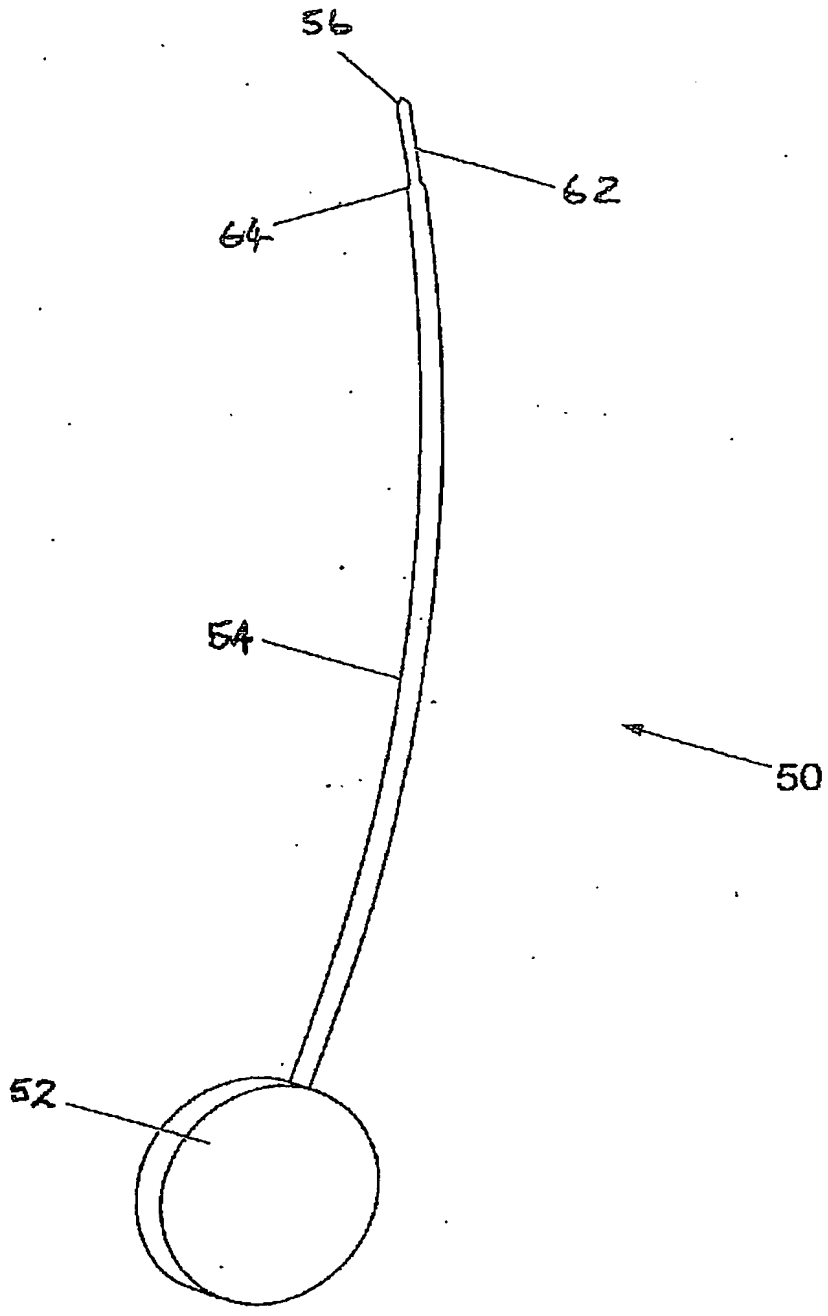


Fig. 5

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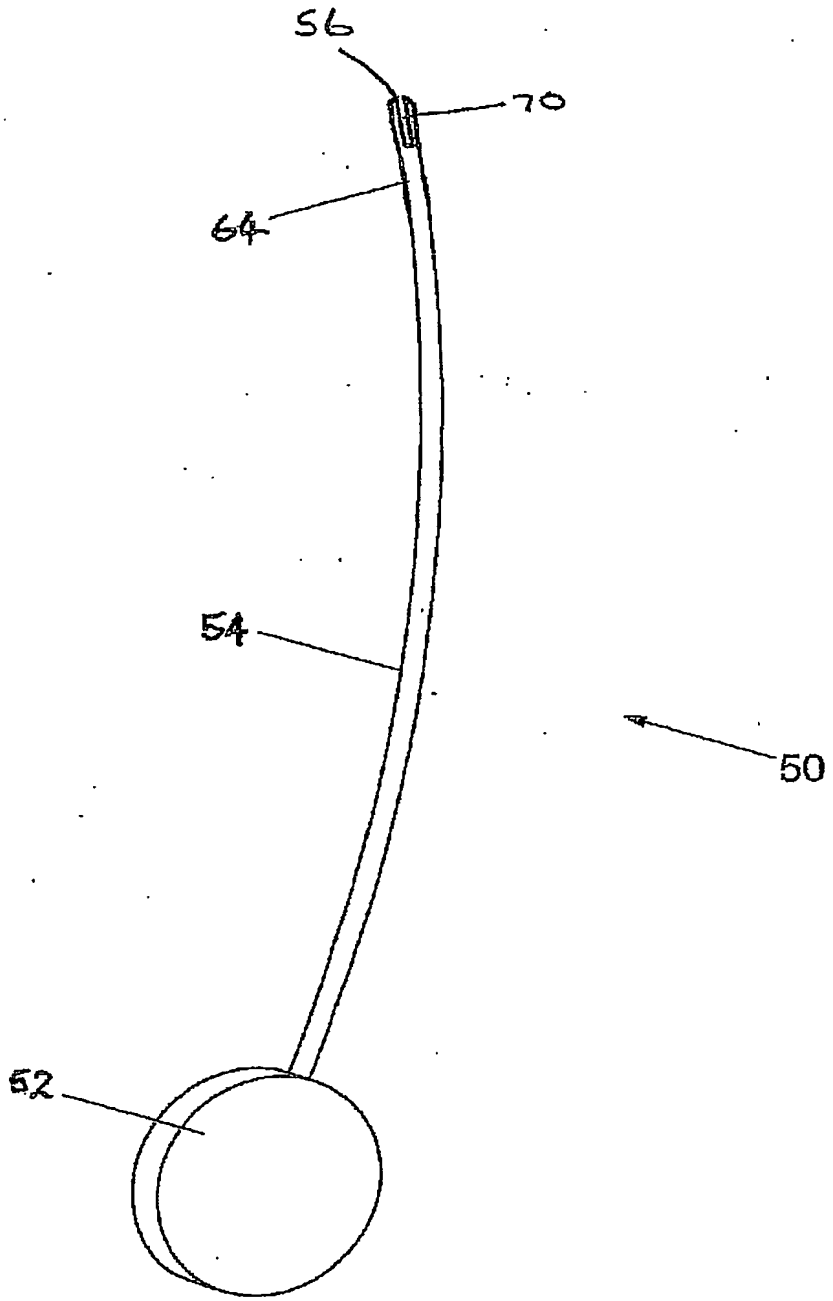

Fig. 6

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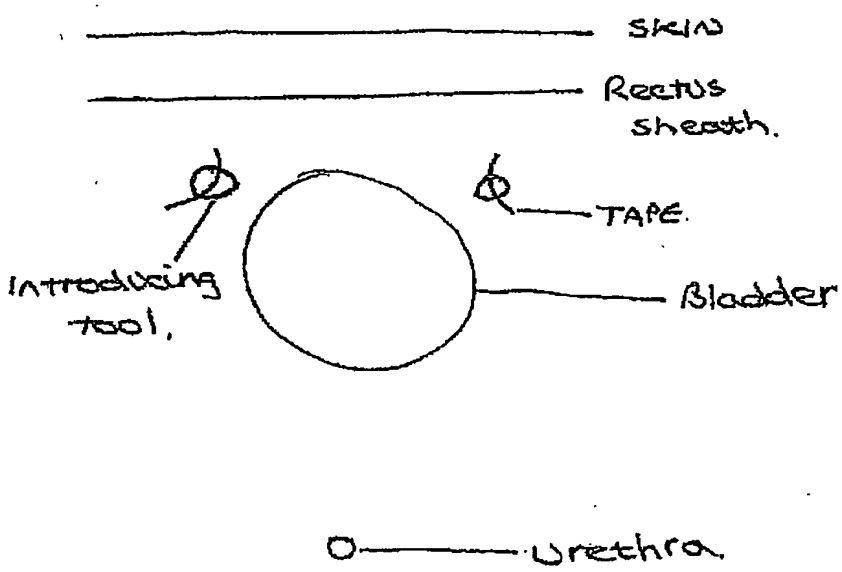
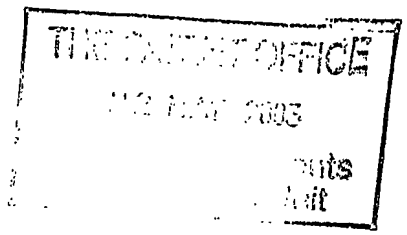
Figure 7.

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